

JAP7 Rec'd PCT/PTO 23 JAN 2006

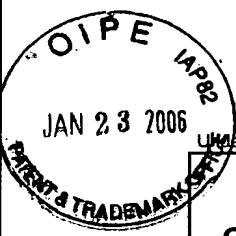
PTO-1390 (Rev. 07-2005)

Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

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JAN 23 2006



**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

532552000800

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

10/551,572 ✓

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/CA2004/000505	2 April 2004	2 April 2003

**TITLE OF INVENTION**  
PHARMACEUTICAL COMPOSITIONS CONTAINING ACTIVE AGENTS HAVING A LACTONE GROUP AND  
TRANSITION METAL IONS

**APPLICANT(S) FOR DO/EO/US**

Paul TARDY

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
- The US has been elected (Article 31).
- A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - is attached hereto (required only if not communicated by the International Bureau).
  - has been communicated by the International Bureau.
  - is not required, as the application was filed in the United States Receiving Office (RO/US).
- An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - is attached hereto.
  - has been previously submitted under 35 U.S.C. 154(d)(4).
- Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - are attached hereto (required only if not communicated by the International Bureau).
  - have been communicated by the International Bureau.
  - have not been made; however, the time limit for making such amendments has NOT expired.
  - have not been made and will not be made.
- An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
- An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

- An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (3 pages)
- An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- A preliminary amendment.
- An Application Data Sheet under 37 CFR 1.76.
- A substitute specification.
- A power of attorney and/or change of address letter.
- A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
- A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U. S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/551,572	INTERNATIONAL APPLICATION NO. PCT/CA2004/000505	ATTORNEY'S DOCKET NUMBER 532552000800																																																																																								
20. <input checked="" type="checkbox"/> Other items or information: PTO/SB/08a/b Form (2 pages plus duplicate) References (29) Return Receipt Postcard																																																																																										
<table border="1"> <tr> <td colspan="2">The following fees have been submitted</td> <td>CALCULATIONS</td> <td>PTO USEONLY</td> </tr> <tr> <td colspan="2">21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="2">22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 All other situations ..... \$200</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="2">23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400 All other situations ..... \$500</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="2">TOTAL OF 21, 22 and 23 =</td> <td>\$ 0.00</td> <td></td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.</td> <td colspan="2" rowspan="2">\$</td> </tr> <tr> <td>Total Sheets</td> <td>Extra Sheets</td> <td>Number of each additional 50 or fraction thereof (round up to a whole number)</td> <td>RATE</td> </tr> <tr> <td>- 100 =</td> <td>/50 =</td> <td></td> <td>x \$250.00</td> </tr> <tr> <td colspan="2">Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).</td> <td colspan="2">\$</td> </tr> <tr> <td>CLAIMS</td> <td>NUMBER FILED</td> <td>NUMBER EXTRA</td> <td>RATE</td> </tr> <tr> <td>Total claims</td> <td>- 20 =</td> <td></td> <td>x</td> </tr> <tr> <td>Independent claims</td> <td>- 3 =</td> <td></td> <td>x</td> </tr> <tr> <td colspan="2">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td colspan="2">+</td> </tr> <tr> <td colspan="2">TOTAL OF ABOVE CALCULATIONS =</td> <td colspan="2">\$ 0.00</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">SUBTOTAL =</td> <td colspan="2">\$ 0.00</td> </tr> <tr> <td colspan="2">Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">TOTAL NATIONAL FEE =</td> <td colspan="2">\$ 0.00</td> </tr> <tr> <td colspan="2">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property</td> <td colspan="2">+</td> </tr> <tr> <td colspan="2">TOTAL FEES ENCLOSED =</td> <td colspan="2">\$ 0.00</td> </tr> <tr> <td colspan="2"></td> <td>Amount to be refunded:</td> <td>\$</td> </tr> <tr> <td colspan="2"></td> <td>Amount to be charged</td> <td>\$</td> </tr> </table>			The following fees have been submitted		CALCULATIONS	PTO USEONLY	21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300		\$		22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 All other situations ..... \$200		\$		23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400 All other situations ..... \$500		\$		TOTAL OF 21, 22 and 23 =		\$ 0.00		<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). 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a.  A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

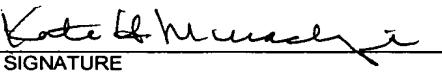
b.  Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ 0.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.

c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. A duplicate copy of this sheet is enclosed.

d.  Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038

**NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.**

SEND ALL CORRESPONDENCE TO:



SIGNATURE

Kate H. Murashige  
MORRISON & FOERSTER LLP  
12531 High Bluff Drive  
Suite 100  
San Diego, California 92130-2040  
(858) 720-5112

Kate H. Murashige

NAME

CUSTOMER NUMBER: 25225

29,959

REGISTRATION NUMBER

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)  
10/551,572INTERNATIONAL APPLICATION NO.  
PCT/CA2004/000505ATTORNEY'S DOCKET NUMBER  
532552000800

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: January 17, 2006Signature:  (Lenay Rogus)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: January 17, 2006 Signature:   
(Lenay Rogus)

Patent  
Docket No. 532552000800

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Paul TARDY

Serial No.: 10/551,572

Filing Date: (Int'l) April 2, 2004

For: PHARMACEUTICAL COMPOSITIONS  
CONTAINING ACTIVE AGENTS  
HAVING A LACTONE GROUP AND  
TRANSITION METAL IONS

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

The document numbers 1, 8-12, 18, 22-26, and 34 listed on the attached Form PTO/SB/08a/b were cited in an International Search Report mailed on September 2, 2004, directed to a counterpart international or foreign application and have not been previously cited.

This Information Disclosure Statement is submitted:

- With the application; accordingly, no fee or separate requirements are required.
- Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - A fee is required. A check in the amount of \_\_ is enclosed.
  - A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.
  - A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 532552000800.

Dated: January 6, 2006

Respectfully submitted,

By Kate H. Murashige  
Kate H. Murashige  
Registration No.: 29,959  
MORRISON & FOERSTER LLP  
12531 High Bluff Drive  
Suite 100  
San Diego, California 92130-2040  
(858) 720-5112

Substitute for form 1449/PTO				<i>Complete if Known</i>	
				Application Number	10/551,572
				Filing Date	(Int'l) April 2, 2004
				First Named Inventor	Paul TARDY
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	532552000800

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
1.	US-5,364,845	11-15-1994	Henderson		
2.	US-5,552,156	09-03-1996	Burke		
3.	US-5,616,341	04-01-1997	Mayer et al.		
4.	US-5,744,158	04-28-1998	Mayer et al.		
5.	US-5,795,589	08-18-1998	Mayer et al.		
6.	US-6,083,530	07-04-2000	Mayer et al.		
7.	US-6,355,268	03-12-2002	Slater et al.		
8.	US-2002/0061870-A1	05-23-2002	Pearson et al.		
9.	US-2002/0131997-A1	09-19-2002	Kartarjian et al.		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
10.	WO-01/85131		11-15-2001	Celator Technologies	
11.	WO-03/028696		04-10-2003	Celator Technologies	
12.	WO-03/028697		04-10-2003	Celator Technologies	

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
13.	AOKI et al., Eur. J. Pharmacol. (2003) 459(2-3):131-138				
14.	BOM et al., Proceedings of the 1999 AACR, NCI, EORTC International Conference				
15.	GIOVANELLA et al., Cancer Res. (1991) 51:3052-3055				
16.	GIOVANELLA et al., Science (1989) 246:1046-1048				
17.	HAAS et al., Clin. Cancer Res. (2003) 9(1):109-114				
18.	HERTZBERG et al., Biochemistry (1989) 28:4629-4638				
19.	HERTZBERG et al., J. Med. Chem. (1989) 32:715-720				
20.	International Search Report for PCT/CA2004/000505, mailed on September 2, 2004, 4 pages				
21.	JAXEL et al., Cancer Res. (1989) 49:1465-1469				
22.	KOSTOVA et al., Archiv Der Pharmazie (2001) 344:157-162				
23.	KOSTOVA et al., European Journal of Medicinal Chemistry (1999) 34:63-68				
24.	KUWAHARA et al., Biochemistry (1986) 25(6):1216-1221				
25.	KUWAHARA et al., Nucleic Acids Symposium Series (1985) 16:201-204				
26.	MANOLOV et al., European Journal of Medicinal Chemistry (1999) 34(10):853-858				

Examiner Signature	Date Considered
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sd-286482

Substitute for form 1449/PTO				<i>Complete if Known</i>	
				Application Number	10/551,572
				Filing Date	(Int'l) April 2, 2004
				First Named Inventor	Paul TARDY
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	532552000800

27.	NISHIMURA et al., Jpn. J. Cancer Chemother (1995) 22:93-97	
28.	OHE et al., J. Nat'l. Cancer Inst. (1992) 84:972-974	
29.	PANTAZIS et al., Cancer Res. (1993) 53:1577-1582	
30.	PANTAZIS et al., Cancer Res. (1992) 52:3980-3987	
31.	PANTAZIS et al., Int. J. Cancer (1993) 53:863-871	
32.	SLICHENMYER et al., Journal of the National Cancer Institute (1993) 85:271-290	
33.	TAKASUNA et al., Folia Pharmacol. Jpn. (1995) 105:447-460	
34.	TENOVUO et al., Journal of Oral Rehabilitation (1997) 24:325-331	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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sd-286482